No. 50022-1-II

COURT OF APPEALS, DIVISION II
OF THE STATE OF WASHINGTON

KING COUNTY CITIZENS AGAINST FLUORIDATION
a nonprofit corporation,
Appellant,

v.

WASHINGTON STATE PHARMACY QUALITY
ASSURANCE COMMISSION, an administrative agency,
Respondent.

REPLY BRIEF OF APPELLANT

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TABLE OF CONTENTS

Page

I. INTRODUCTION 1

II. REPLY TO THE COMMISSION'S RESTATEMENT OF THE ISSUES 3

III. COMMENTS ON THE COMMISSION'S COUNTERSTATEMENT OF THE CASE 5

IV. ARGUMENT 8

A. Response To Commission's "Standard Of Review" Argument 8

B. The Supreme Court And Court Of Appeals Have Not Decided Whether "Public" And "Bottled" Fluoridated Waters And Their Fluoridating Additives Are Drugs Under Relevant State Statutes 9

1. *Kaul v. City of Chehalis* ("*Kaul*"), 45 Wn.2d 616, 277 P.2d 352 (1954) 9

a. Request to Overrule, Clarify, Or Distinguish *Kaul* 13

2. *Protect the Peninsula's Future v. City of Port Angeles* ("*Protect the Peninsula's Future*"), 175 Wn.App 201, 304 P.3d 914 (2013), *rev denied*, 178 Wn.2d 1022, 312 P.3d 651 (2013) 14

a. Request to Overrule, Clarify, Or Distinguish *Protect The Peninsula's Future* 18

i. If *Protect the Peninsula's Future* Cannot Adequately Be Clarified And/Or Distinguished, It Should Be Overruled 21

C. This Court Should Decide That "Public" And "Bottled" Fluoridated Waters And Their Fluoridating Additives Are Drugs Under Relevant State Drug Statutes 22

1. The Commission Is The Agency Deciding Whether A Substance Is A Drug In Intrastate Commerce 23

D. This Court Should Find That The Trial Court Abused Discretion When It Struck Paragraphs 11-16 From the Judicial Petition 24

V. CONCLUSION 25

DECLARATION OF SERVICE 26

ATTACHMENTS

TABLE OF AUTHORITIES

Table of Cases

Page

16 *Bunch v. King County Dept. of Youth Services*, 155 Wn.2d 165, 116 P.3d 381 (2005)

9 *Children's Hosp. and Medical Center v. Washington State Dept. of Health*, 95 Wn.App. 858, 975 P.2d 567 (1999)

13 *City of Port Angeles v. Our Water-Our Choice!* ("*City of Port Angeles*"), 170 Wn.2d 1, 239 P.3d 589 (2010)

8 *Estate of Ackerley v. Department of Revenue*, 187 Wn.2d 906, 389 P.3d 583 (2017)

10 *Fosbre v. State*, 70 Wn.2d 578, 424 P.2d 901 (1967)

passim *Kaul v. City of Chehalis* ("*Kaul*"), 45 Wn.2d 616, 277 P.2d 352 (1954)

8 *Northwest Sportfishing Industry Association v. Washington State Department of Ecology*, 172 Wn.App. 72, 288 P.3d 677 (2012)

9 *Pendergrast v. Matichuk*, 186 Wn.2d 556, 379 P.3d 96 (2016)

passim	*Protect the Peninsula's Future v. City of Port Angeles* ("*Protect the Peninsula's Future*"), 175 Wn.App. 201, 304 P.3d 914 (2013), *rev. denied*, 178 Wn.2d 1022, 312 P.3d 651 (2013)
16	*State v. Osman*, 168 Wn.2d 632, 229 P.3d 729 (2010)
23	*State ex rel. Evergreen Freedom Foundation v. Washington Educ. Ass'n*, 140 Wn.2d 615, 999 P.2d 602 (2000)
8	*Squaxin Island Tribe v. Wash. State Dep't of Ecology*, 177 Wn.App. 734, 312 P.3d 766 (2013)
16	*Tingey v. Haisch*, 159 Wn.2d 652, 152 P.3d 1020 (2007)

RCW

4, 24	18.64.005(1)
4, 24	18.64.005(6)
4, 22, 23, 24	18.64.005(7)
2, 3, 4 , 6, 7, 10, 11, 13, 17, 19, 20, 25	Former 18.64.010
25	18.64.011(14)
4, 9, 11, 12, 21	18.64.011(14)(b)
5	18.64.011(14)(c)
4, 9, 11, 12, 21	18.64.011(14)(d)
11	Former 18.64.080
11	Former 18.64.250
8	34.05.570(4)(c)
8	34.05.570(4)(c)(ii)
8	34.05.570(4)(c)(iii)
5	Former 69.04.008(3)

3, 5, 11, 12, 13, 14, 15, 16, 17, 19, 20, 21, 22, 25	Former 69.04.009
6, 15, 19, 20, 25	69.04.009
4, 9, 11, 12, 21	69.04.009(2)
5	69.04.009(3)
4. 9, 11, 12, 21	69.04.009(4)
24	69.04.040(4)
24	69.04.050 to -.070
24	69.04.570
23, 24	69.04.570 to -.640
23	69.04.600
4, 24	69.04.730
4, 9, 11, 12, 21	69.41.010(10)(b)
5	69.41.010(10)(c)
4, 9, 11, 12, 21	69.41.010(10)(d)

RAP

5	10.3(5)

I. INTRODUCTION

The Brief of Appellant ("App. Br.") raises two major questions. The first asks if "bottled" fluoridated waters and their fluoridating additives are drugs under state law when the intended use is mitigation, treatment, or prevention of tooth decay disease. (App. Br. at 5) The second asks if "public" fluoridated waters and their fluoridating additives are drugs under state law when the intended use is mitigation, treatment, or prevention of tooth decay disease. (*Id.*) These questions should both be answered in the affirmative.

In the Brief of Respondent ("Res. Br."), the Washington State Pharmacy Quality Assurance Commission ("Commission") mischaracterizes the issues when it focuses only on the fluoridating additives and fails to adequately address "bottled" and "public" fluoridated waters. The Res. Br. at 1 correctly characterizes the limited nature of the Commission's Decision when it states, "the Commission concluded that fluoridating substances added to drinking water are not drugs." The Commission's Decision at AR148[1] does only address the "fluoridating substances" and not the "fluoridated waters." The Petition to the Commission addressed "public" and "bottled" fluoridated waters and their fluoridating additives. (AR21)

The Res. Br. at 2 in its Restatement of the Issues focuses on the issue "of whether fluoride added to drinking water is a drug." The alleged controlling caselaw associated with this restated issue is *Kaul* and *Protect the Peninsula's Future*. (Res. Br. at 2) But each of these cases only addresses

[1] This Reply uses the same abbreviations for citation to the record that are used in the Brief of Appellant ("App. Br."). (*See* App. Br. at 1, Note 1, and at 2, Note 3)

"city" ("public") fluoridated tap water and neither addresses "bottled" fluoridated water products with a drug claim on the bottle. (AR90-113) As stated in the App. Br. at 1, whether "bottled" fluoridated waters and their fluoridating additives are drugs under state law when there is a drug claim on the bottles' labels is an issue of first impression in Washington State. This Court should find it arbitrary and capricious that the Commission Decision on bottled fluoridated water was not reasonably based on caselaw and was made without analysis of relevant drug statutes. (App. Br. at 3 and 50)

The Commission argues that it is without authority to determine if a substance is a drug in intrastate commerce. (Res. Br. at 14-17) But a plain language reading of the state statutory scheme regarding drugs shows that this Commission authority is "necessarily implied." (App. Br. at 11-12)

A careful reading of *Kaul* and *Protect the Peninsula's Future* in consideration of the record before this Court does not lead to the conclusion that "public" fluoridated waters are never drugs. Regarding *Kaul*, the *Kaul* Court does not explicitly state that the City of Chehalis fluoridated waters or its fluoridating additives are not drugs. (AR102-06; *Kaul* at 617-25) It only states that the "assignment of error" regarding "selling drugs" was "not well taken." (AR106; *Kaul* at 625) Apparently, Mr. Kaul argued to the trial court that the City was "engaging in selling drugs as defined in [former] RCW 18.64.010." (App. Br. at 19) When the trial court found that the City was "not engaging in selling drugs as defined in [former] RCW 18.64.010," Mr. Kaul assigned error. (*Id.*) But Mr. Kaul did not argue this error and the *Kaul* Court found it "not well taken" for that reason. (App. Br. at 17-26) So while the trial court conclusion stands that the City of Chehalis was "not engaging

in selling drugs as defined in [former] RCW 18.64.010," this did not amount to a ruling by the *Kaul* Court that the City's fluoridated waters or fluoridating additives were not drugs under former RCW 69.04.009, the only state statute that defined a drug when Mr. Kaul's challenges were being considered. Neither the briefing before the *Kaul* Court (AR46-89) nor the Decision in *Kaul* (AR102-06; *Kaul* at 617-25) mentions or analyzes RCW 69.04.009.

The *Protect the Peninsula's Future* Court correctly found the "not well taken" language in *Kaul* was not dicta (AR97) and that a holding that the City was "engaging in selling drugs as defined in [former] RCW 18.64.010" (AR106) "would have resulted in a different outcome" (AR97) in that Mr. Kaul would have prevailed on that minor assignment of error, but the *Protect the Peninsula's Future Court* did not explicitly find that the Cities' fluoridated waters and fluoridating additives were not drugs. (AR93-100) On this matter, that Court only found that the trial court, without knowledge of the *Kaul* Court briefing, had not abused discretion in denying a motion to amend the complaint. (AR97-98)

As the App. Br. demonstrates, a plain language analysis of state drug statutes requires the conclusion that "public" and "bottled" fluoridated waters and their fluoridating additives are drugs when the intended use is mitigation, treatment, or prevention of tooth decay disease.

II. REPLY TO THE COMMISSION'S RESTATEMENT OF THE ISSUES

Regarding Restatement Issue 1 in the Res. Br. at 2, *Kaul* (*Kaul v. City of Chehalis*, 45 Wn.2d 616, 625, 277 P.2d 352 (1954)) has only relevant controlling caselaw that the City of Chehalis was "not engaging in selling

drugs as defined in [former] RCW 18.64.010." (App. Br. at 19; AR106) *Protect the Peninsula's Future* (*Protect the Peninsula's Future v. City of Port Angeles*, 175 Wn.App. 201, 304 P.3d 914 (2013), *rev. denied*, 178 Wn.2d 1022, 312 P.3d 651 (2013)) has only relevant controlling caselaw that a trial court, without knowledge of the *Kaul* Court briefing, does not abuse discretion when it relies on its interpretation of *Kaul* to conclude that its futile to allow amendment of a complaint asking the trial court to declare that the Cities "public" fluoridated waters and fluoridating additives are drugs. (AR97-98) Neither *Kaul* nor *Protect the Peninsula's Future* stand generally as controlling authority for "public" fluoridated waters and their fluoridating additives never being drugs under RCW 69.04.009(2) and (4), RCW 18.64.011(14)(b) and (d), and RCW 69.41.010(10)(b) and (d).

Further, neither *Kaul* nor *Protect the Peninsula's Future* address "bottled" fluoridated waters at all and neither stand as controlling authority for "bottled" fluoridated waters and their fluoridating additives never being drugs under the same drug statutes.

Regarding Restatement Issue 2 in the Res. Br. at 2, the Commission acted outside its statutory authority when it failed to apply the statutory framework in RCW 69.04.009(2) and (4), RCW 18.64.011(14)(b) and (d), and RCW 69.41.010(10)(b) and (d) in consideration of its authority to regulate drugs in RCW 69.04.730 and in RCW 18.64.005(1), -(6), and -(7). The Commission, which had the briefing relied upon by the *Kaul* Court in its administrative record, erroneously applied the caselaw in *Kaul* and *Protect the Peninsula's Future.*

Regarding Restatement Issue 3 in the Res. Br. at 2, the Commission acted in an arbitrary and capricious manner when it applied *Kaul* and *Protect the Peninsula's Future* to determine that "bottled" fluoridated water with a drug claim would not be a drug based on Commission reliance on the definition of drugs in RCW 18.64.011(14)(c), former RCW 69.04.008(3)[2], and RCW 69.41.010(10)(c). (*See* Res. Br. at 12, Note 1) *Kaul* and *Protect the Peninsula's Future* only address "public" fluoridated waters and not "bottled" fluoridated waters with a drug claim.

III. COMMENTS ON THE COMMISSION'S COUNTERSTATEMENT OF THE CASE

In its Counterstatement of the Case in the Res. Br. at 3-6, the Commission fails to limit itself to presenting facts and procedure as required by RAP 10.3(5).[3] Instead, it presents the following arguments:

> Recognizing that their petition was contrary to existing case law . . . [citing to *Kaul*]

(Res. Br. at 3) It is the position of Citizens (Appellant King County Citizens Against Fluoridation) that the "not well taken" language in *Kaul* at 625 (AR106) is misinterpreted by the Commission and that Citizen's petition is not contrary to *Kaul*.

The *Kaul* Court did not consider the issue of whether the City's "public" fluoridated water was a drug under former RCW 69.04.009, because as the briefing before the *Kaul* Court (AR46-89) demonstrates, there was no

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[2] Current RCW 69.04.009(3).

[3] Statement of the Case. A fair statement of the facts and procedure relevant to the issues presented for review, without argument. Reference to the record must be included for each factual statement. (RAP 10.3(5))

assignment of error that raised that issue. In relevant part, the *Kaul* Court states:

> Appellant's remaining assignments of error . . . that the city is not engaged in selling drugs . . . as defined by *statute* [is] not well taken.

(*Kaul* at 625; AR106 (emphasis supplied)) Nowhere in the *Kaul* decision is the referenced state drug *statute* identified. But the *Kaul* decision makes it clear that the relevant state drug *statute* is the *statute* identified in "Appellant's remaining assignments of error." The App. Br. at 19 quotes the relevant assignment of error and establishes that the referenced *statute* is former RCW 18.64.010. As the App. Br. at 19-20 establishes, Mr. Kaul did not argue this assignment of error.

The Rulemaking Petition told the Commission that Mr. Kaul's briefing failed to argue this assignment of error and for this reason "it was not considered on appeal and 'not well taken.'" (App. Br. at 18-19; AR24) The App. Br. at 25 argues:

> Former RCW 18.64.010 did not have a definition of "selling" or "sale" or "drugs" when *Kaul* was decided. (Attachment A2 [to the App. Br.]) This may be why Appellant Kaul abandoned this assignment of error in his legal argument.

There is no basis in the *Kaul* decision or in the briefing before the *Kaul* Court (and the Commission has identified no such basis) to conclude that *Kaul* decided the issue of whether fluoridated waters and their fluoridating additives are drugs as defined in RCW 69.04.009. The Res. Br. at 3 misinterprets *Kaul* when it argues that Citizens recognized its petition was contrary to existing caselaw in *Kaul*.

The Res. Br. at 3 then argues:

> *Kaul* held that fluoridating substances in drinking water are not drugs . . .

Kaul did not hold generally that fluoridating substances in drinking water are not drugs. (*Supra* at 2-3) *Kaul* only let stand the trial court's conclusion that the City was "not engaging in selling drugs as defined in [former] RCW 18.64.010" only because this assignment of error was not supported by argument in the brief of Mr. Kaul. (*Id.*)

The Res. Br. at 3 next argues:

> Citizens Against Fluoridation characterized this portion of the *Kaul* decision as dicta

Neither the agency petition (AR19-89) nor the Brief of Appellant characterizes any portion of the *Kaul* decision as dicta.

Next, the Res. Br. at 4 argues:

> [The *Protect the Peninsula's Future*] Court did not agree with the Citizens Against Fluoridation's reading of *Kaul*, stating "[b]ecause a holding that fluoridated waters are drugs would have resulted in a different outcome, *Kaul*'s statement is not dicta."

Appellants in *Protect the Peninsula's Future* argued that *Kaul*'s statement about drugs was dicta. [*Protect the Peninsula's Future* at 215; AR97) Citizens does not make that argument. (App. Br.)

In addition to including argument in its Counterstatement of the Case, the Commission also misstates facts. The Res Br. at 4 states:

> Citizens Against Fluoridation claimed that the federal Food and Drug Administration (FDA) declared fluoridating substances added to drinking water and fluoridated bottled water to be drugs. Clerk Papers (CP) at 100:1-20.

CP100:1-20 does state that the FDA recently ruled that bottled fluoridated water is a drug when a claim is made that the water is intended to prevent

tooth decay disease. (CP100:7-10) The FDA has a petition before it requesting the "FDA to find that all fluoridation chemical additives and fluoridated drinking waters are drugs pursuant to federal law when the intended use is to aid in the prevention of tooth decay disease." (CP100:10-14) The FDA has not yet ruled on that petition. (CP100:15 "FDA will decide that issue")

IV. ARGUMENT

A. Response To Commission's "Standard Of Review" Argument

The Commission argues that relief will only be granted to Citizens "under the extraordinary grounds identified in RCW 34.05.570(4)(c)." (Res. Br. at 6-7) The Commission cites to two cases for the proposition that the grounds are "extraordinary": *Northwest Sportfishing Industry Association v. Washington State Department of Ecology*, 172 Wn.App. 72, 90, 288 P.3d 677 (2012); and *Squaxin Island Tribe v. Wash. State Dep't of Ecology*, 177 Wn.App. 734, 740, 312 P.3d 766 (2013). Neither case refers to the provisions in RCW 34.05.570(4)(c) as "extraordinary grounds."

The grounds relied upon by Citizens are in RCW 34.05.570(4)(c)(ii) ("outside the statutory authority of the agency or the authority conferred by a provision of law [i.e. contrary to law]" and -(iii) ("arbitrary or capricious"). The review on both of these grounds is *de novo*. (Res. Br. at 8; *Estate of Ackerley v. Department of Revenue*, 187 Wn.2d 906, 909, 389 P.3d 583 (2017); *Northwest Sportfishing Industry Association* at 90)

While this Court must give "due deference ... to the specialized knowledge and expertise of an administrative agency" (*Northwest Sportfishing Industry Association* at 91), as stated in the Res. Br. at 7, this

Court should give no deference, as stated in the App. Br. at 10, to an agency interpretation of a statute where the language of the statute is unambiguous. (*Children's Hosp. and Medical Center v. Washington State Dept. of Health*, 95 Wn.App. 858, 869, 975 P.2d 567 (1999))

Citizens suggests that to decide that "public" and "bottled" fluoridated waters and their fluoridating additives are drugs under the conditions specified in RCW 18.64.011(14)(b) and (d), RCW 69.04.009(2) and (4), and RCW 69.41.010(10)(b) and (d), it will not be necessary to overrule parts of *Kaul* or *Protect the Peninsula's Future*. But if an Appellate Court finds this necessary then the standard of review is provided by *Pendergrast v. Matichuk*, 186 Wn.2d 556, 565, 379 P.3d 96 (2016):

> This court will not overturn precedent without either a clear showing that an established rule is incorrect and harmful, or a clear showing that the legal underpinnings of the precedent have been eroded.

(citations and punctuation omitted)

B. The Supreme Court And Court Of Appeals Have Not Decided Whether "Public" And "Bottled" Fluoridated Waters And Their Fluoridating Additives Are Drugs Under Relevant State Statutes

The Res. Br. at 9 argues that the Supreme Court in *Kaul* and the Court of Appeals in *Protect the Peninsula's Future* decided fluoridating substances added to drinking water are not drugs. This is a misinterpretation of *Kaul* and *Protect the Peninsula's Future*.

1. *Kaul v. City of Chehalis* ("*Kaul*"), 45 Wn.2d 616, 277 P.2d 352 (1954)

The *Kaul* Court does not explicitly state that the City of Chehalis fluoridated water or fluoridating additives are not drugs. It only states that the "assignment of error" raised by Mr. Kaul regarding "selling drugs" was "not

well taken." (AR106; *Kaul* at 625) Apparently, Mr. Kaul argued to the trial court that the City was "engaging in selling drugs as defined in [former] RCW 18.64.010." (App. Br. at 19) When the trial court found that the City was "not engaging in selling drugs as defined in [former] RCW 18.64.010," Mr. Kaul assigned error. (*Id.*; AR57) But Mr. Kaul failed to support this assignment of error with legal argument.[4] (AR46-69) As stated in the Rulemaking Petition and in the App Br., "If a party fails to support assignments of error with legal arguments, they will not be considered on appeal." (*Howell v. Spokane & Inland Empire Blood Bank*, 117 Wn.2d 619, 624, 818 P.2d 1056 (1991); *Fosbre v. State*, 70 Wn.2d 578, 583, 424 P.2d 901 (1967)) (AR24, App. Br. at 18-19, 21, and 29) The *Kaul* Court found the "selling drugs" assignment of error "not well taken" for this reason. (App. Br. at 17-26)

As stated in the App. Br. at 19-22, the most obvious demonstration that the "assignment of error" regarding "selling drugs as defined in [former] RCW 18.64.010" was not argued is found on AR48 where it states that a citation to [former] "RCW 18.64.010" only appears on page 17 of Mr. Kaul's brief. This page only lists assignments of error without supporting legal argument. (AR57)

The most obvious reason that Mr. Kaul's brief did not argue that the City was "selling drugs as defined in [former] RCW 18.64.010" is that [former] RCW 18.64.010 did not have a definition of "selling" or "sale" or "drugs" when *Kaul* was under review. (App. Br. at 25) Attachment A2 to

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[4] The City of Chehalis also did not argue this "assignment of error." (AR70-89)

the App. Br. provides a copy of former RCW 18.64.010, which states that this statute was last amended in 1935 when the substance was then "codified in RCW 18.64.080 and 18.64.250." Former RCW 18.64.080 and 18.64.250 did not have a definition of "selling" or "sale" or "drugs" when *Kaul* was under review. (App. Br. Attachments A3-A6) So, without a definition of "selling drugs" in former RCW 18.64.010 (or in the statutes where it was recodified), Mr. Kaul could not have succeeded in arguing that the City of Chehalis was "selling drugs as defined in [former] RCW 18.64.010."

So while the trial court conclusion should stand that the City of Chehalis was "not engaging in selling drugs as defined in [former] RCW 18.64.010," this does not amount to a ruling by the *Kaul* Court that the City's fluoridated waters or fluoridating additives were not drugs under former RCW 69.04.009, the only state statute that defined a drug between 1945 (App. Br. Attachment A25) and 1963 when RCW 18.64.011 was adopted (AR139-41). Neither the briefing before the *Kaul* Court (AR46-89) nor the *Kaul* decision (AR102-06; *Kaul* at 617-25) mentions, considers, or analyzes former RCW 69.04.009. (*See* AR24-25)

So, based on the briefing in *Kaul* which clarifies the "selling drugs" assignment of error, it remains an issue of first impression for this Court as to whether both "public" and "bottled" fluoridated waters and their fluoridating additives are drugs under state statutes that now include RCW 69.04.009(2) and (4), RCW 18.64.011(14)(b) and (d), and RCW 69.41.010(10)(b) and (d). A plain language analysis of these statutes requires the conclusion that both "public" and "bottled" fluoridated waters are drugs if they are intended for use in the mitigation, treatment, or prevention of tooth

decay disease. (App. Br. at 13-15) If such waters are intended for use in the mitigation, treatment, or prevention of tooth decay disease, then their component fluoridating additives are also drugs under a plain language analysis of RCW 69.04.009(4), RCW 18.64.011(14)(d), and RCW 69.41.010(10)(d). (App. Br. at 14-15) Also any fluoridating additives that are themselves intended for use in the mitigation, treatment, or prevention of tooth decay disease are drugs under a plain language analysis of RCW 69.04.009(2), RCW 18.64.011(14)(b), and RCW 69.41.010(10)(b). (App. Br. at 15)

If the issue had been raised before the trial court and then argued before, and decided by, the *Kaul* Court[5] of whether City of Chehalis fluoridated waters and its fluoridating additives were drugs under former RCW 69.04.009, the result "would not have affected any [major] outcomes of the *Kaul* majority including that the City had police power to fluoridate and that none of Mr. Kaul's constitutional rights were violated." (App. Br. at 23) The only impact of such a ruling would have been a requirement that the City of Chehalis comply with applicable drug laws and regulations. (*Id.* at 23)

The Res. Br. at 3 and 9 argues that Citizens characterized a portion of the *Kaul* decision at dicta. While the appellant in *Protect the Peninsula's Future* argued that portions of the *Kaul* decision are dicta, Citizens does not make that argument. (*Supra* at 3 and 7)

In summary, nothing in the *Kaul* decision answers the question of whether "public" or "bottled" fluoridated waters and their fluoridating

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[5] None of which actually occurred.

additives are drugs under any state statute that actually defines drugs. In consideration of the *Kaul* Court briefing, included in the administrative record before the Commission at AR46-89, it is clear that the "assignment of error" regarding "selling drugs" that the *Kaul* Court found "not well taken" was that the City of Chehalis was "not engaging in selling drugs as defined in [former] RCW 18.64.010." (*Supra* at 2-3, and 5-6) The likely reasons for finding this "assignment of error . . . not well taken" were that it was not supported by legal argument and that "selling" and "drugs" were not defined in former RCW 18.64.010. (*Supra* at 10-11) Nevertheless, with the *Kaul* Court briefing before the Commission, it was clear that *Kaul* did not rule that the City of Chehalis was not engaging in selling drugs as defined in former RCW 69.04.009

The decision in *City of Port Angeles* (*City of Port Angeles* v. Our Water-Our Choice!, 170 Wn.2d 1, 239 P.3d 589 (2010) supports this conclusion as discussed in the App. Br. at 28. The Res. Br. at 9-10 misinterprets the *Kaul* decision when the Commission states *Kaul* is "binding precedent on the question of whether fluoridating substances added to drinking water are drugs."

a. Request to Overrule, Clarify, Or Distinguish *Kaul*

In the App. Br. at 2, Citizens states that if this Court finds that *Kaul* is binding precedent that fluoridated waters and their fluoridating additives are not drugs under relevant state drug laws, then Citizen's intends to file a Petition for Review with the State Supreme Court.

2. *Protect the Peninsula's Future v. City of Port Angeles* ("*Protect the Peninsula's Future*"), 175 Wn.App 201, 304 P.3d 914 (2013), *rev denied*, 178 Wn.2d 1022, 312 P.3d 651 (2013)

The *Protect the Peninsula's Future* Court also does not explicitly state that the City of Forks and the City of Port Angeles "public" fluoridated waters or fluoridating additives are not drugs. Instead, relevant to the instant case, the *Protect the Peninsula's Future* Court only finds that the trial court, without knowledge of the *Kaul* Court briefing, did not abuse discretion when the trial court denied petitioners' request to amend its complaint to add a request that the trial court declare that the Cities' fluorides were drugs. (*Protect the Peninsula's Future* at 214; App. Br. at 28-29)

The *Kaul* Court briefing, that is in the administrative record for the instant case, was not in the record before the *Protect the Peninsula's Future* Court. The *Protect the Peninsula's Future* Court and the trial court for that case were tasked with interpreting this statement in the *Kaul* decision:

> Appellant's remaining assignments of error . . . that the city is not engaged in selling drugs . . . as defined by *statute* [is] not well taken.

(*Kaul* at 625; AR106 (emphasis supplied)) The *Kaul* decision did not quote the assignment of error regarding "selling drugs" and did not cite, or in any way identify, the *statute* relied upon in this assignment of error anywhere in the *Kaul* decision. However the *Kaul* Court did use the language "drugs . . . as defined by *statute*." (*Id.* (emphasis supplied)) There was only one statute between 1945 and 1963 that defined drugs and that was former RCW 69.04.009. (*Supra* at 11)

The *Protect the Peninsula's Future* Court and the trial court for that

case appear to have reasonably concluded as a factual matter that the unidentified *statute* was former RCW 69.04.009, the only statute that actually defined drugs when *Kaul* was decided. (AR97; *Protect the Peninsula's Future* at 215, Note 11 ("Since *Kaul* was decided, the legislature has not changed the definition of "drug" in RCW 69.04.009 in any way that affects our analysis."))

The *Protect the Peninsula's Future* Court used the "abuse of discretion" standard of review:

> We review a trial court's ruling on a motion to amend the complaint for an abuse of discretion. A trial court abuses its discretion when its decision is manifestly unreasonable, based on untenable grounds, or made for untenable reasons.

(AR 97; *Protect the Peninsula's Future* at 214 (citations omitted))

> The trial court denied the motion on the grounds that it would be futile, given that fluorides in public drinking water were held not to be drugs in *Kaul.*

(AR97; *Protect the Peninsula's Future* at 214-15) Without access to the briefing before the *Kaul* Court, Citizens suggests that under the abuse of discretion standard, the *Protect the Peninsula's Future* Court was correct in finding that the trial court did not abuse discretion in denying the motion to amend compliant. (App. Br. at 31)

It is a heavy burden for an appellant to prevail in an abuse of discretion challenge. (App. Br. at 31)

> "Discretionary" is commonly defined as involving an exercise of judgment and choice, not an implementation of a hard-and-fast rule, and "discretion" as the latitude of decision within which a court or judge decides questions arising in a particular case not expressly controlled by fixed rules of law according to the circumstances and according to the judgment of the court or judge.

(*State v. Osman*, 168 Wn.2d 632, 640, 229 P.3d 729 (2010) (punctuation and citations omitted))

If a trial court is not obviously unreasonable and uses plausible[6] legal reasoning, it is not an abuse of discretion. (App. Br. at 31) The *Protect the Peninsula's Future* Court applied this abuse of discretion standard. (*Supra* at 15)

The standard of review on whether the Commission acted contrary to law in the instant case is *de novo*. (App. Br. at 9; *supra* at 8) The *de novo* standard is "less deferential" to the Commission. (*Bunch v. King County Dept. of Youth Services*, 155 Wn.2d 165, 176, 116 P.3d 381, (2005) (*de novo* is "less deferential standard of review")

The *Protect the Peninsula's Future* Court did not have the *Kaul* Court briefing before it. Without that briefing, it reasonably assumed under the abuse of discretion standard that the trial court did not abuse discretion when it interpreted the statement in *Kaul* at 625 that the assignment of error "that the city is not engaged in selling drugs . . . as defined by *statute* [is] not well taken" to mean that *Kaul* found "fluorides in public drinking water" not to be drugs under former RCW 69.04.009. (*See Protect the Peninsula's Future* at 215, including Note 11; AR97)

However, the *Kaul* Court briefing was submitted to the Commission and the Rulemaking Petition demonstrated that the "selling drugs"

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[6] "Plausible" is defined as "having an appearance of truth or reason; seemingly worthy of approval or acceptance; credible; believable. Webster's Encyclopedic Unabridged Dictionary (2001) is used for all dictionary definitions in Appellant's Briefs. "When a term has a well-accepted, ordinary meaning, a regular dictionary may be consulted to ascertain the term's definition. (*Tingey v. Haisch*, 159 Wn.2d 652, 658, 152 P.3d 1020 (2007) (citations omitted))

assignment of error was not supported by legal argument in the Brief of Appellant and for that reason the assignment of error to the trial court's conclusion that the City of Chehalis was "not engaging in selling drugs as defined in [former] RCW 18.64.010" was "not well taken." (AR24) The *Kaul* briefing makes clear that the *Kaul* decision did not amount to a general finding that fluorides in drinking water were never drugs under other state drug statutes.

The *Protect the Peninsula's Future* Court, in relevant part, was only tasked with determining if the trial court, without knowledge of the *Kaul* Court briefing, abused discretion in interpreting *Kaul* to hold that fluorides in drinking water were not drugs under former RCW 69.04.009. (*Protect the Peninsula's Future* at 214-15) Under the record before the *Protect the Peninsula's Future* Court, Citizens believes that the appellate court was correct in finding no abuse of discretion. However, if the *Protect the Peninsula's Future* Court would have had the *Kaul* Court briefing in its record along with the argument that was in the Rulemaking Petition at AR22-28, then Citizen's believes that the *Protect the Peninsula's Future* Court would have been required by law to find that the trial court abused discretion if the trial court still denied the amendment to the compliant.

With similar reasoning, this Court should find that because the Commission had the *Kaul* Court briefing in its record along with the argument that was in the Rulemaking Petition at AR22-28, that the Commission acted in an arbitrary or capricious manner and in a manner contrary law when it misinterprets *Kaul* and misinterprets the abuse of discretion rulings in *Protect the Peninsula's Future.* In consideration of the

Kaul Court briefing, it cannot reasonably be found that *Kaul* and *Protect the Peninsula's Future* stand for the proposition that "public" and "bottled" fluoridated waters and their fluoridating additives are never drugs under state drug statutes even when the intended use of such waters is mitigation, treatment, or prevention of tooth decay disease.

a. Request to Overrule, Clarify, Or Distinguish *Protect The Peninsula's Future*

In the Brief of Appellant at 30, Citizens requests that this Court overrule, clarify, or distinguish *Protect the Peninsula's Future*. As Citizens demonstrates (*supra* at 9-13) *Kaul* is not "binding precedent on the question of whether fluoridating substances added to drinking water are drugs" as claimed in the Res. Br. at 10. To the degree that *Protect the Peninsula's Future* at 216 and 220 found *Kaul* was "binding precedent" "that fluorides in drinking water are not drugs under Washington law" *Protect the Peninsula's Future* should be distinguished, clarified, or overruled.

Protect the Peninsula's Future may be distinguished and limited to the facts that were before that Court when it interpreted *Kaul* because it did not have the *Kaul* Court briefing before it. *Protect the Peninsula's Future* at 216 interprets *Kaul* to state that "fluorides in drinking water are not drugs under Washington law." (AR97) But without the *Kaul* Court briefing, neither the *Protect the Peninsula's Future* Court nor the Commission would be able to determine which "Washington law" or *statute* that the *Kaul* Court analyzed or considered. *Kaul* at 625 (AR 106), in relevant part, only states it found the "selling drugs" assignment of error "not well taken." However, based on the *Kaul* Court briefing, it is evident that this "assignment of error"

only considered former RCW 18.64.010. (AR57) RCW 18.64.010 did not have a definition of "selling" or "sale" or "drugs." (App. Br. at 6 and 10-11)

The Commission had the *Kaul* Court briefing in its administrative record. (AR46-89) The Commission knew or should have known that the statute that the *Kaul* Court was referring to was former RCW 18.64.010 and not former RCW 69.04.009, the only Washington law that defined drugs at that time.

Therefore, with the *Kaul* Court briefing in its record, the Commission acted in an arbitrary or capricious manner and in a manner contrary law when it misinterprets *Kaul* and *Protect the Peninsula's Future* and assumes that the "Washington law" in *Kaul* referenced by *Protect the Peninsula's Future* at 216 was former RCW 69.04.009 instead of former RCW 18.64.010.

The other relevant comments regarding *Kaul* in *Protect the Peninsula's Future* may be resolved by clarification because the *Protect the Peninsula's Future* Court never explicitly states that *Kaul* found that the City was not selling drugs as defined by RCW 69.04.009. *Protect the Peninsula's Future* at 214-15 correctly quotes:

> The trial court denied the motion on the grounds that it would be futile, given that fluorides in public drinking water were held not to be drugs in *Kaul*.

That is a correct statement of what the trial court did but not a statement that the Court confirmed except to find that the trial court did not abuse discretion.

Protect the Peninsula's Future at 215, Note 11, discusses RCW 69.04.009 but that discussion can be considered dicta because RCW 69.04.009 is not actually relevant in *Kaul*. (App. Br. at 45-46)

Protect the Peninsula's Future at 215 states that *Kaul*'s "not well taken" statement is not dicta, and Citizens agrees but this just means that the trial court's conclusion in *Kaul* that the City was "not engaging in selling drugs as defined in [former] RCW 18.64.010" is not reversed. This also does not address whether the City was selling drugs as defined in RCW 69.04.009.

Protect the Peninsula's Future at 216 states that for "purposes of [appellants'] motion to amend her complaint, drug is defined by RCW 69.04.009 and applicable Washington case law." That was the purpose of appellants' motion but RCW 69.04.009 was not addressed in *Kaul.*

Protect the Peninsula's Future at 220 states, "Even if binding precedent had directly controlled the outcome of this appeal," which suggests that the *Protect the Peninsula's Future* Court did not find the outcome controlled by "binding precedent" in *Kaul.*

Protect the Peninsula's Future at 220 also states, "we must apply binding precedent" which is true but the only relevant binding precedent in *Kaul* was that the *Kaul* Court let stand the trial court's conclusion that the City was "not engaging in selling drugs as defined in [former] RCW 18.64.010."

This Court should find that *Kaul* is the relevant controlling caselaw and that the *Kaul* Court briefing is necessary to understand that the *Kaul* Court only addressed "selling drugs" as defined in former RCW 18.64.010 and not as defined in former RCW 69.04.009. This Court should find that the *Protect the Peninsula's Future* Court's interpretation of *Kaul* can be clarified and distinguished because that Court was not given the *Kaul* Court briefing and did not actually contradict *Kaul.* The Commission had the *Kaul* Court

briefing, and it misinterprets *Kaul* when it states categorically at AR148 that "fluoridating substances used in drinking water, including bottled water, are not drugs." The Commission should be found to have acted in an arbitrary or capricious manner and in a manner contrary law. This Court should do a plain language analysis of the unambiguous statutes in RCW 69.04.009(2) and (4), RCW 18.64.011(14)(b) and (d), and RCW 69.41.010(10)(b) and (d) and conclude that fluoridated waters (bottled or public) and their fluoridating additives are drugs when the intended use of such waters is mitigation, treatment, or prevention of tooth decay disease.

i. If *Protect the Peninsula's Future* Cannot Adequately Be Clarified And/Or Distinguished, It Should Be Overruled

If *Protect the Peninsula's Future* cannot adequately be clarified and/or distinguished, it should be overruled. If this Court finds that *Protect the Peninsula's Future* misinterprets *Kaul* because *Protect the Peninsula's Future* states or implies that *Kaul* decided "that fluorides in drinking water are not drugs under Washington law [former RCW 69.04.009], then this Court should overrule *Protect the Peninsula's Future* on this issue.

Overturning precedent is appropriate if there is "a clear showing that the legal underpinnings of the precedent have been eroded." (*Supra* at 9) The *Kaul* Court briefing provides a clear showing that the statute considered when the *Kaul* Court found the "selling drugs" assignment of error "not well taken" was not former RCW 69.04.009.

Also, this Court can find that overturning precedent is appropriate under the alternative finding that there is "a clear showing that an established rule is incorrect and harmful. (*Supra* at 9) The *Kaul* Court briefing shows

that it is incorrect to tie the "selling drugs" assignment of error that was "not well taken" in *Kaul* to former RCW 69.04.009. It is harmful because it prevents state regulation of fluoridated waters and their fluoridating additives as drugs which avoids "the protection and promotion of the public health, safety, and welfare" that the legislature intended by putting the Commission in charge of regulating drugs. (See RCW 18.64.005(7); AR34)

C. This Court Should Decide That "Public" And "Bottled" Fluoridated Waters And Their Fluoridating Additives Are Drugs Under Relevant State Drug Statutes

The App. Br. demonstrates that under a plain meaning analysis of relevant unambiguous state drug statutes, fluoridated drinking water (bottled or public) is a drug "*if*" it is intended for use in the mitigation, treatment, and/or prevention of tooth decay disease in human beings. (*See e.g.* App. Br. at 13-15) If fluoridated drinking waters are drugs then, under a plain meaning analysis of relevant unambiguous state drug statutes, their fluoridating additives are drugs. (*Id.*) When this Court confirms that *Kaul* did not decide that fluoridated drinking water and their fluoridating substances are not drugs under former RCW 69.04.009, then this Court should proceed to a plain meaning analysis of the relevant unambiguous state drug statutes. This Court should find that fluoridated drinking waters and their fluoridating additives are drugs when the waters are intended for use in the mitigation, treatment, and/or prevention of tooth decay disease in human beings. The Res. Br. does not argue that a plain meaning analysis of the relevant state drug statutes does not support this conclusion. The Res. Br. does not reach this issue because of its misinterpretation of *Kaul*.

1. The Commission Is The Agency Deciding Whether A Substance Is A Drug In Intrastate Commerce

The Commission argues that it is not the agency deciding whether a substance is a drug in intrastate commerce. (Res. Br. at 14) The Commission cites to RCW 69.04.570 to RCW 69.04.640 as the laws for "intrastate recognition of a 'new drug.'" (*Id.*) These laws provide the process for approval of "new drugs." For example, RCW 69.04.600 (attachment 1 hereto) authorizes the director [which is defined in RCW 69.04.006 to be "the director of the department of agriculture of the state of Washington and his or her duly authorized representatives"] to "issue an order refusing to permit [a new drug] application to become effective." But the Commission fails to consider RCW 69.04.730 (attachment 2 hereto) which requires the director to designate the Commission "to carry out all of the provisions of [Chapter 69.04] pertaining to drugs." (App. Br. at 11-12) So it is the Commission and not the director who is to carry out the provisions of RCW 69.04.570 to RCW 69.04.640.

The Commission is also directed by RCW 18.64.005(7) (AR34) to "Promulgate rules for . . . drugs," (App. Br. at 11) which necessarily implies that the Commission has authority to determine if a substance is a drug.[7] So the Commission is the agency with the authority to determine if a substance is a drug by applying the definitions of drugs in state statutes. Citizens is not seeking new drug approval but just seeking a ruling that fluoridated drinking waters and their fluoridating additives are drugs under state drug statutes if

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[7] *State ex rel. Evergreen Freedom Foundation v. Washington Educ. Ass'n*, 140 Wn.2d 615, 634, 999 P.2d 602 (2000) ("The powers of an administrative agency are derived from statutory authority expressly granted or necessarily implied.")

the intended use is mitigation, treatment or prevention of tooth decay disease.

The Res. Br. at 15 argues that Citizens "assumes the Commission has the same legal authority as the FDA." Citizens is aware of the differences in legal authority. But under RCW 69.04.730 and RCW 18.64.005(1), -(6), and -(7) the Commission has "expressly granted" authority to regulate drugs and that "necessarily implies" authority to interpret state drug statutes to determine if a substance is a drug that it can regulate.

The Res. Br. at 17 argues that the Commission does not have authority to regulate "new drugs" that have not been approved as "new drugs." But that is within the Commission's authority in RCW 69.04.570 to RCW 69.04.640 in light of RCW 69.04.730. RCW 69.04.040(4) prohibits introduction into intrastate commerce of any new drug in violation of RCW 69.04.570 and RCW 69.04.050 to -.070 provide for enforcement and penalties. RCW 69.04.730 gives the Commission "authority to promulgate regulations for the efficient enforcement" of these statutes. With regard to fluoridated drinking waters and their fluoridating additives, an essential step toward efficient enforcement of drug statutes is a determination that these substances are drugs when the waters are intended for use in the mitigation, treatment, or prevention of tooth decay disease. This is the conclusion that should be reached by this Court by using a plain meaning analysis of the relevant drug statutes.

D. This Court Should Find That The Trial Court Abused Discretion When It Struck Paragraphs 11-16 From the Judicial Petition

In the App. Br. at 46-49, Citizens argues that this Court should find that the trial court abused discretion when it struck Paragraphs 11-16 from the

judicial petition. The Commission has expressed no objection in the Res. Br. The App. Br. at 48 quotes from Citizens' Motion to Supplement the Record which is now at CP204-05, the Motion Reply is now at CP211-17 and the First Declaration of Julie Simms is now at CP206-10.

V. CONCLUSION

Kaul at 625 found:

> Appellant's remaining assignments of error . . . that the city is not engaged in selling drugs . . . as defined by statute [is] not well taken.

Citizens requests that this Court find that the referenced "statute" was former RCW 18.64.010 and not former RCW 69.04.009 and find that this "selling drugs" assignment of error was not argued in Mr. Kaul's Brief of Appellant. Because *Kaul* did not decide that fluoridated drinking waters and their fluoridating additives were not drugs under former RCW 69.04.009, this should be an issue of first impression by this Court.

Citizens requests that this Court do a plain language analysis of RCW 69.04.009 and RCW 18.64.011(14) and find that public and bottled fluoridated waters and their fluoridating additives are drugs when the intended use is mitigation, treatment, or prevention of tooth decay disease. With the Kaul Court briefing in the record, this Court should find that the Commission acted in an arbitrary and capricious manner and contrary to law.

Dated the 8th day of September, 2017.

Respectfully submitted,

Gerald Steel, WSBA #31084
Attorney for Citizens

DECLARATION OF SERVICE

I, GERALD STEEL, under penalty of perjury under the laws of the State of Washington declare as follows: I am the attorney for Appellant herein. On September 8, 2017, by email sent by COA2 File Upload Manager Div-2eDocManagers@courts.wa.gov, I caused the *Reply Brief of Appellant* with this *Declaration of Service* to be served on:

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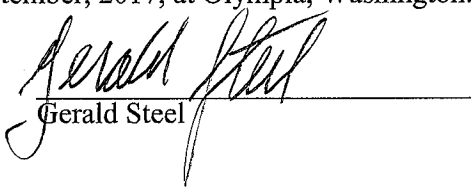
DATED this 8th day of September, 2017, at Olympia, Washington.



Gerald Steel

ATTACHMENTS

PAGES	
1	RCW 69.04.600
2	RCW 69.04.730

RCW 69.04.600

Denial of application.

If the director finds, upon the basis of the information before him or her and after due notice and opportunity for hearing to the applicant, that the drug, subject to the application, is not safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, he or she shall, prior to such effective date, issue an order refusing to permit such application to become effective and stating the findings upon which it is based.

[**2012 c 117 § 339; 1945 c 257 § 78;** Rem. Supp. 1945 § 6163-127.]

RCW 69.04.730

Enforcement, where vested—Regulations.

The authority to promulgate regulations for the efficient enforcement of this chapter is hereby vested in the director: PROVIDED, HOWEVER, That the director shall designate the pharmacy quality assurance commission to carry out all the provisions of this chapter pertaining to drugs and cosmetics, with authority to promulgate regulations for the efficient enforcement thereof.

[2013 c 19 § 51; 1947 c 25 § 91 (passed notwithstanding veto); 1945 c 257 § 91 (vetoed); Rem. Supp. 1947 § 6163-139a.]

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